PARCHE DE LEON- lidocaine, menthol patch
Pharmadel LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Parche Leon Gel Patch (SHANGHAI G)

Drug Facts

Active Ingredients & Purpose

Active ingredients (in each patch)	***Purpose***
Lidocaine 4%	External analgesic
Menthol 1%	External analgesic

Uses

For the temporary relief of pain.

Warnings

FOR EXTERNAL USE ONLY. Avoid contact with the eyes.

Do not use

- in large quantities, particularly over raw surfaces or blistered areas
- on sensitive skin
- if allergic to any ingredients in this product

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present

If pregnant of breast-feeding

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults & children 12 years of age and older:** apply to affected area not more than 3 to 4 times daily
- **children under 12 years of age:** consult a doctor

- clean dry affected area

- remove patch from film

- apply sticky side of patch to affected area

- use one patch at a time

- leave patch on affected area for up to 8-hours at a time

Other Information

- store at room temperature 59-86 F (15-30 C)
- do not store in direct sunlight or expose to excessive heat

TAMPER EVIDENT: Do not use if packet containing the patch is torn or broken.

Inactive Ingredients

dihydroxyaluminum aminoacetate anhydrous, edetate disodium, glycerin, hydroxyacetophenone, kaolin, mineral oil, polyacrylic acid,

polysorbate 80, propylene glycol, povidone k90, sodium polyacrylate, tartaric acid, titanium dioxide, water

Principal Display Panel

5 Patches (5.5 in x 3.94 in (13.97 cm x 10 cm) each)
- Maximum Strength
- Fast Acting pain relief
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PARCHE DE LEON

lidocaine, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	

POVIDONE K90 (UNII: RDH86HJV5Z)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYACRYLIC ACID (800000 MW) (UNII: D0I6NSZ87U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-040-05	5 in 1 CARTON	03/18/2022	
1	NDC:55758-040-01	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:55758-040-01	1 in 1 POUCH; Type 0: Not a Combination Product	03/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/18/2022	

Labeler - Pharmadel LLC (030129680)

Revised: 12/2022 Pharmadel LLC